IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SHIRE LLC, and SUPERNUS PHARMACEUTICALS, INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., and MYLAN INC., Defendants.	C. A. No. _____

COMPLAINT

Plaintiffs Shire LLC and Supernus Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Defendants" or "Mylan"), hereby allege as follows:

1. Shire LLC ("Shire") is a corporation organized and existing under the laws of the State of Kentucky, having a principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

2. Supernus Pharmaceuticals, Inc. ("Supernus") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

3. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma") is a West Virginia corporation, and a wholly-owned subsidiary and agent of Defendant Mylan Inc., having a principal place of business at 781 Chestnut Ridge Road,

Morgantown, West Virginia 26505. Upon information and belief, Defendant Mylan Pharma manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Mylan Inc. ("Mylan Inc.") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Defendant Mylan Inc., itself and through its wholly-owned subsidiary and agent Defendant Mylan Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of U.S. Patent Nos. 6,287,599 B1 ("the '599 patent") and 6,811,794 B2 ("the '794 patent") (Exhibit A and Exhibit B, respectively). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, Defendants are in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Defendant Mylan Inc. conducts its North American operations, in part, through Defendant Mylan Pharma. Together, they collaborate in developing, manufacturing, marketing, and selling generic drugs throughout the United States, including in this judicial district.

8. This Court has personal jurisdiction over Defendant Mylan Pharma, by virtue of, *inter alia*, its incorporation under the laws of the State of West Virginia, and because it maintains its principal place of business in the State of West Virginia.

9. This Court has personal jurisdiction over Defendant Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of West Virginia, including through its wholly-owned subsidiary and agent Defendant Mylan Pharma, a West Virginia corporation. Furthermore, Mylan Inc. is registered to do business in the State of West Virginia and has appointed a registered agent for service of process in the State of West Virginia. Mylan Inc. (formerly known as Mylan Laboratories Inc.) has also previously availed itself of this Court by asserting counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this jurisdiction. *See, e.g.*, *Novartis Pharms. Corp. v. Mylan Pharms. Inc., et al.*, C.A. No. 11-00015-IMK; *Alza Corp. v. Mylan Labs. Inc., et al.*, C.A. No. 03-00158-IMK.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

THE PATENTS-IN-SUIT

11. On September 11, 2001, the '599 patent, entitled "Sustained Release Pharmaceutical Dosage Forms with Minimized pH Dependent Dissolution Profiles," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). Supernus is the record owner of the '599 patent. Shire has an exclusive license under the '599 patent with regard to pharmaceutical products containing the active ingredient guanfacine or salts thereof.

12. On November 2, 2004, the '794 patent, entitled "Sustained Release Pharmaceutical Dosage Forms with Minimized pH Dependent Dissolution Profiles," was duly and legally issued by the USPTO. Supernus is the record owner of the '794 patent. Shire has an exclusive license under the '794 patent with regard to pharmaceutical products containing the active ingredient guanfacine or salts thereof.

13. Shire holds New Drug Application ("NDA") No. 022037 for guanfacine hydrochloride extended release tablets, 4 mg. Shire markets these tablets in the United States under the trade name "INTUNIV®." The '599 and '794 patents are each listed in the U.S. Food

and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for INTUNIV®.

ACTS GIVING RISE TO THIS ACTION

14. Upon information and belief, Defendant Mylan Pharma, on behalf of itself and as agent for Defendant Mylan Inc., submitted Abbreviated New Drug Application ("ANDA") No. 202-578 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, and sale of guanfacine hydrochloride extended release tablets, 4 mg ("Mylan's ANDA Product"). ANDA No. 202-578 specifically seeks FDA approval to market Mylan's ANDA Product prior to the expiration of the '599 patent and the '794 patent (collectively, "the patents-in-suit").

15. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Mylan Pharma certified in ANDA No. 202-578 that the claims of the patents-in-suit will not be infringed by the manufacture, use, or sale of Mylan's ANDA Product. Defendants provided written notification of ANDA No. 202-578 and its § 505(j)(2)(A)(vii)(IV) certification by sending Plaintiffs a letter bearing a date of February 8, 2011.

COUNT 1 – INFRINGEMENT OF THE '599 PATENT

16. Plaintiffs reallege Paragraphs 1-15 as if fully set forth herein.

17. Mylan Pharma's submission of ANDA No. 202-578 to the FDA, on behalf of itself and as agent for Defendant Mylan Inc., constitutes infringement of the '599 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports the Mylan ANDA Product, or induces or contributes to any such conduct, Mylan Pharma would further infringe the '599 patent under 35 U.S.C. §271(a), (b), and/or (c).

18. Mylan Inc. is jointly and severally liable for Mylan Pharma's infringement of the '599 patent. Upon information and belief, Mylan Inc. participated in, contributed to, aided, abetted, and/or induced Mylan Pharma's submission of ANDA No. 202-578 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA. Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 202-578 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA constitutes infringement of the '599 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports the Mylan ANDA Product, or induces or contributes to any such conduct, Mylan Inc. would further infringe the '599 patent under 35 U.S.C. §271(a), (b), and/or (c).

19. Defendants Mylan Inc. and Mylan Pharma were aware of the existence of the '599 patent prior to filing ANDA No. 202-578.

20. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 2 – INFRINGEMENT OF THE '794 PATENT

21. Plaintiffs reallege Paragraphs 1-20 as if fully set forth herein.

22. Mylan Pharma's submission of ANDA No. 202-578 to the FDA, on behalf of itself and as agent for Defendant Mylan Inc., constitutes infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports the Mylan ANDA Product, or induces or contributes to any such conduct, Mylan Pharma would further infringe the '794 patent under 35 U.S.C. §271(a), (b), and/or (c).

23. Mylan Inc. is jointly and severally liable for Mylan Pharma's infringement of the '794 patents. Upon information and belief, Mylan Inc. participated in, contributed to, aided, abetted, and/or induced Mylan Pharma's submission of ANDA No. 202-578 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA. Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 202-578 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA constitutes infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports the Mylan ANDA Product, or induces or contributes to any such conduct, Mylan Inc. would further infringe the '794 patent under 35 U.S.C. §271(a), (b), and/or (c).

24. Defendants Mylan Inc. and Mylan Pharma were aware of the existence of the '794 patent prior to filing ANDA No. 202-578.

25. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '599 and '794 patents;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202-578 shall not be earlier than the expiration date of the last to expire of the '599 and '794 patents, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from engaging in the commercial manufacture, use, offer to sell, or sale within the United States and its territories, or importation into the United States and its

territories, of Mylan's ANDA product identified in this Complaint, and any other products that infringe the '599 and '794 patents, prior to the expiration of the last to expire of the '599 and '794 patents, including any extensions;

D. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur in prosecuting this action; and

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: April 20, 2011

SCHRADER, BYRD & COMPANION, PLLC

/s/ John Porco

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